

REMARKS/ARGUMENTS

Reconsideration and allowance in view of the following remarks are respectfully requested.

Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable under Wilk in combination with McNeely, et al. Applicant respectfully traverses this rejection.

Independent Claim 1, the sole independent claim pending in this Application, relates to a method including forming an incision in a target wall segment in the digestive tract and advancing a distal end of a flexible conduit so that the distal end of the conduit extends through said wall. Claim 1 also provides that after forming the incision and before advancing the conduit through it, the incision is dilated with an inflatable balloon to facilitate passage of the conduit therethrough. Further, Claim 1 provides that after the incision is formed and after the distal end of the flexible conduit is advanced through the wall, the distal end of the conduit is anchored with respect to the wall.

As will be understood from a close examination of Wilk, Wilk does not teach advancing the distal end of his flexible conduit through an incised target wall segment of the digestive tract and then anchoring the distal end with respect to the wall. Indeed, the flexible conduit Wilk teaches as advanced into the stomach is never advanced through the wall of the stomach. Rather, it is "anchored" to the wall by applying suction to hold the conduit against the wall. Wilk does not specifically disclose how a seal is maintained between the tubular member and the wall, although it is schematically illustrated in Figure 5A. Wilk does teach inserting a hollow needle through the tubular member and through the wall into the abdominal cavity, inserting an incising instrument, and moving the distal end of an endoscope through the

perforation, but the tubular member itself is never passed through the incision. Rather, it is anchored against the inner wall surface.

Because Wilk does not teach advancing a distal end of a flexible conduit through an incision in the target wall segment and, after advancing the flexible conduit through the wall, anchoring the distal end of the flexible conduit with respect to that wall, Wilk does not teach a method such as claimed "except the specific mentioning of dilating the opening after it is made" as alleged by the Examiner.

The Examiner cites the secondary reference to McNeely as allegedly teaching a method of dilating a stomach wall. Actually, it is believed that McNeely has been mischaracterized in this regard. Indeed, McNeely relates to the insertion of a gastrostomy catheter through a passageway formed through both the abdominal and stomach walls of the patient. In McNeely, the abdominal wall is anchored at two points with respect to the stomach wall, and then a passage for the gastrostomy catheter is created, including using a dilation catheter assembly. Thus, McNeely does not simply teach a method of dilating the stomach wall, but relates to a procedure required for placement of a gastrostomy catheter through both the abdominal wall and the stomach wall.

As noted above, Wilk teaches passing various incising devices through a tubular member that is anchored by suction to the inner wall surface of the stomach. Wilk does not relate to the placement of a gastrostomy catheter and McNeely does not teach or in any way suggest that dilation of the incision(s) made in Wilk would be necessary or desirable. It is therefore respectfully submitted that in the first instance, the Examiner has not established that the skilled artisan, in the absence of Applicant's disclosure, would have been taught by McNeely that dilation of the Wilk incision would have been necessary or desirable. In any event, even if an incision made by Wilk through the stomach wall is dilated with a dilation catheter in view of McNeely's teachings, the resulting combination of Wilk and McNeely does not teach or suggest the method

specifically recited in Applicant's independent claim 1 because the combination of Wilk and McNeely does not teach passing the tubular member of Wilk through a dilated incision in the digestive tract wall, and then anchoring the flexible tube with respect to the stomach wall. As noted above, Wilk teaches anchoring the flexible tube to the inner surface of the stomach wall before any incision is made, and never teaches passing the tubular member through the stomach wall. For all these reasons, Claim 1 is not obvious from Wilk taken in combination with McNeely.

With respect to claims 13 and 15, Applicant respectfully traverses the Examiner's summary conclusion that it would have been obvious to situate the dilating balloon on a needle knife conduit. Firstly, neither Wilk nor McNeely teach or suggest an endoscopic knife device comprising a conduit within which a needle-knife is disposed. Moreover, neither of these documents in any way teach or suggest the unique combination of Claims 18 and 19, wherein the conduit of the needle-knife receives a guide wire and an inflatable balloon is provided on the conduit of the needle-knife device. Wilk refers only generally to a piercing needle at the distal end of the tubular instrument and endoscopic incising instruments, but nowhere describes a needle knife retractable through a needle knife conduit so as to be exchangeable with a guide wire and/or a dilatable balloon on the needle knife conduit. McNeely teaches an introducer needle for penetrating the abdomen and stomach and for placement of the guide wire, and then a dilation catheter separately placed over the guide wire. Thus, McNeely also fails to teach or suggest incorporating the dilatable balloon on the conduit of a needle knife.

Clearly, then, the specific instrument used in the method of the invention as set forth in Claims 13, 15, 17, 18 and 19, is nowhere taught or suggested by the combination of Wilk and McNeely, and the Examiner has failed to establish that a needle knife device as recited in the method of these dependent claims was known or would have been an obvious choice at the time of Applicant's invention. Applicant therefore respectfully traverses the Examiner's summary conclusion of obviousness and respectfully requests that the Examiner cite evidence in support of his otherwise

unsubstantiated conclusion that the use of such an instrument in the method of the invention would have been obvious.

For all the reasons advanced above, reconsideration and withdrawal of the rejection over Wilk and McNeely is solicited.

Claims 6 and 14 were rejected as unpatentable over Wilk in view of McNeely and further in view of Laufer. Applicant respectfully traverses this rejection.

The Examiner asserts that in view of Laufer it would have been obvious to use a cauterizing incision device and/or balloon sealing means in the method of Wilk/McNeely. Applicant respectfully but strongly disagrees. As noted above, Wilk clearly teaches, and it is evidently central to Wilk's method, that his tubular member is sealed by suction to the inner wall of the patient's stomach. Wilk never teaches or suggests that the tubular member should be passed through the stomach wall. Quite the contrary, Wilk teaches only that instruments pass through the suction sealed tubular member to and through the stomach wall. Under these circumstances, it would not have been obvious to provide balloons on Wilk's tubular member or to anchor Wilk's tubular member using balloons. Wilk's simply relates to an entirely different attachment process, and, without the benefit of knowledge of Applicant's disclosure and claims, the skilled artisan would not obviously redesign Wilk's method as the Examiner has alleged.

In view of the foregoing, reconsideration and withdrawal of the rejection of Claims 6 and 14 is solicited.

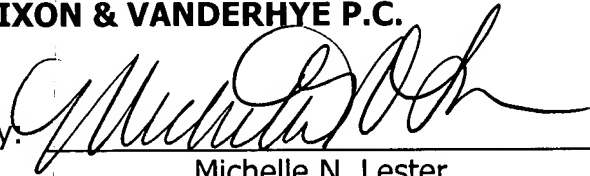
KALLOO et al
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All objections and rejections having been addressed, it is respectfully submitted that the present Application is in condition for allowance, and a Notice to that effect is solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By.

A handwritten signature in black ink, appearing to read "Michelle N. Lester", written over a horizontal line.

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